

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

<b>In re: SUBOXONE ANTITRUST LITIGATION</b>	<b>MDL No. 2445</b>
<b>THIS DOCUMENT RELATES TO:</b>  <b>Direct Purchaser Class Actions</b>	<b>Master Docket No. 2:13-md-02445-MSG</b>

**DIRECT PURCHASER PLAINTIFFS' MEMORANDUM IN OPPOSITION TO  
DEFENDANTS' MOTION TO DISMISS DIRECT PURCHASER PLAINTIFFS'  
CONSOLIDATED AMENDED CLASS ACTION COMPLAINT**

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## INTRODUCTION

Reckitt<sup>1</sup> made approximately \$1 billion per year on its brand name prescription drug Suboxone because the drug was unlike anything else, changing the way the health care community could treat a pervasive health problem: opioid (*e.g.*, heroin) dependence. But then Reckitt gamed the system. Reckitt knew Suboxone, sold in tablet form, would soon face competition from less expensive generic versions of the drug. So Reckitt hatched a multi-pronged anticompetitive scheme. First, it performed a product hop; that is, Reckitt (1) introduced a “new” (but no better) film form of the drug, (2) fraudulently convinced doctors to switch to the new film form by falsely stating the tablets had significant safety concerns that the film overcame, and (3) withdrew the old tablet form from the market. Second, using a so-called “citizen” petition to the FDA and by sabotaging the creation of a shared Risk Evaluation and Mitigation Strategy (“REMS”) among itself and its would-be generic competitors, Reckitt wrongfully delayed FDA approval of therapeutically equivalent (“AB-rated”) but less expensive generic versions of Suboxone tablets. Between the product hop and the delay, by the time those less expensive generic tablet versions were finally approved, many months later than they otherwise would have been, almost all doctors were prescribing the film version of Suboxone.

Reckitt’s switching the form of Suboxone blocked less-expensive generic tablets from the cost-efficient channel of distribution: automatic substitution at the pharmacy counter. Federal and state laws permit — and often require — pharmacists to substitute a less-expensive AB-rated generic for the brand drug. But to be AB-rated, a generic must be in the same dosage form as the brand drug. Cheaper generic Suboxone *tablets*, while clinically identical, cannot be substituted

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<sup>1</sup> Defendants here include Reckitt Benckiser, Inc., Reckitt Benckiser, LLC, Reckitt Benckiser Pharmaceuticals, Inc., Reckitt Benckiser Healthcare (UK) Ltd., and Reckitt Benckiser Group, plc, collectively referred to as “Reckitt.” The direct purchaser plaintiffs are Burlington Drug Co. Inc., Rochester Drug Co-Operative Inc., and Meijer Inc. and Meijer Distribution, Inc. (“plaintiffs”).

by a pharmacist for more expensive Suboxone *film*. Pharmacists cannot fill prescriptions for Suboxone film with less expensive generic tablets. This is why Reckitt introduced Suboxone film. In short, Reckitt intentionally disrupted the automatic substitution mechanism designed by Congress and state generic substitution laws to foster competition and lower prices for prescription drug consumers, and thereby inflicted antitrust injury — overcharges — on purchasers of Suboxone.

Because of Reckitt's illegal, anticompetitive conduct, generic Suboxone tablets did not launch until March 2013, many months after they would have absent Reckitt's illegal, anticompetitive conduct. When they did launch, those generic tablets were blocked from the cost-efficient means of distribution, the AB-rated automatic pharmacy substitution mechanism, thereby preventing patients from obtaining the lower prices Congress and state substitution laws intended. Consequently, the direct purchaser plaintiffs allege violations of the Sherman Act, 15 U.S.C. § 2, for overcharges stemming from the unlawful scheme to delay and impede generic competition to Suboxone.

Reckitt's motion is remarkable for what it concedes. Reckitt concedes that “[i]f the introduction of a new product by a monopolist actually delayed the advent of generic competition *and* otherwise made no economic sense, then there might be a claim of antitrust injury based on that exclusion.”<sup>2</sup> Plaintiffs' complaint alleges both. Reckitt essentially concedes the allegations of intentional sabotage of the REMS process, as well: “Reckitt had attempted to work with the generics for less than a year, and would have *lost* money if the attempt had succeeded. No monopolist can be required to shoot itself in the foot.”<sup>3</sup> Reckitt's attempt to

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<sup>2</sup> Reckitt Br. at 21-22 (emphasis in original).

<sup>3</sup> *Id.* at 26 (emphasis in original).

explain its petition — which led FDA to refer the matter to the Federal Trade Commission — suffers from the same infirmities. Nor does Reckitt have any answer to controlling law holding that its actions in combination state a claim for an anticompetitive scheme even if they may not state separate standalone antitrust claims. Reckitt’s motion should therefore be denied.

## FACTS

### **A. FDA regulations and the federal statutory structure create the backdrop for Reckitt’s conduct.**

#### **1. Generic drugs and generic drug competition benefit purchasers.**

Generic competition enables purchasers, at all levels of the drug supply chain, to purchase generic versions of a brand drug at substantially lower prices. Generic competition to a brand drug can bring billions of dollars in savings to drug purchasers.<sup>4</sup>

Typically, the first AB-rated generic drug<sup>5</sup> is priced significantly below its brand counterpart, and as more AB-rated generics enter and the generics compete with each other, drug prices decline further. The “AB” rating, together with the automatic substitution mechanism established under the state generic substitution laws and regulations, permits pharmacists to automatically substitute the lower-priced generic drug for the brand drug; all states have generic substitution laws and regulations that allow such substitution, and most states’ laws require it, recognizing that generic competition and automatic generic substitution of brand drugs results in substantially lower prices for purchasers.<sup>6</sup> A generic often captures 80% or more of the

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<sup>4</sup> Compl. ¶¶ 51, 53. Citations to the “Complaint” or “Compl.” are to the Consolidated Amended Class Action Complaint and Demand for Jury Trial, filed August 15, 2013 (ECF No. 47).

<sup>5</sup> AB-rated generics are those that the Food and Drug Administration (“FDA”) has determined are therapeutic equivalents (*i.e.*, bioequivalent in that they deliver the same amount of active ingredient(s) to the body) and pharmaceutical equivalents (*i.e.*, have the same milligram strength, dosage form, and route of administration) to a corresponding brand name drug. Compl. ¶ 43.

<sup>6</sup> Compl. ¶¶ 43, 50, 54.

corresponding brand drug's sales within the first several months after launch. Brand drug manufacturers thus have powerful incentives to delay or block generic competition for as long as possible.<sup>7</sup>

**2. The Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act facilitate the approval of generic drugs.**

In 1984, the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act ("FDCA") changed the approval standards for generic drugs. Through these amendments, Congress sought to expedite the market entry of generic drugs and reduce healthcare expenses nationwide while also protecting brand drug companies' incentives to create new products. A generic manufacturer seeking approval to sell a generic version of a brand drug may file an Abbreviated New Drug Application ("ANDA") with FDA. If an ANDA applicant establishes that the generic drug is bioequivalent to the brand drug, the ANDA may rely on the scientific findings of safety and effectiveness included in the brand drug manufacturer's original NDA.<sup>8</sup>

**3. The FDA can require safety materials to accompany a drug and encourages a single set of such materials for brand and generic versions of a drug.**

The FDA may require drug manufacturers to develop Risk Evaluation and Mitigation Strategies ("REMS") to ensure that a drug's benefits outweigh its risks. REMS are particularly applicable for drugs that have a high potential for abuse. A REMS can include a medication guide, package insert, and potential restrictions on the distribution of the drug (such as allowing dispensing of the drug only in select facilities or by practitioners with special certifications).<sup>9</sup> The FDA can withhold ANDA approval until an appropriate REMS has been created for a generic drug product, and can require that generic ANDA sponsors coordinate with the brand

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<sup>7</sup> Compl. ¶¶ 9, 51, 53.

<sup>8</sup> Compl. ¶¶ 38-44.

<sup>9</sup> Compl. ¶ 57.

drug manufacturer to create a Single Shared REMS program (“SSRS”) for purposes of uniformity — an identical program for use with both the brand and AB-rated generic equivalents.<sup>10</sup> Brand drug manufacturers can delay ANDA approval by obstructing efforts by generic manufacturers to develop an SSRS program for the brand drug and its generic equivalents, knowing (1) the FDA will not approve an ANDA for a generic drug without the development of a REMS program and (2) that a Single Shared REMS is preferred but requires the cooperation of the brand manufacturer.<sup>11</sup>

**4. The FDA’s petition process facilitates the raising of genuine issues of clinical therapeutic importance.**

Through a citizen petition, anyone may express concerns to the FDA about safety, scientific, or legal issues regarding a product at any time and may request that the FDA take, or refrain from taking, any administrative action. The FDA considers the petition and any associated documents, including comments or objections, and renders a decision based on the science relating to the relevant drug product. To have a chance of success with the FDA, the petition must include supportive, clinically meaningful data, and the requested relief must be consistent with the Hatch-Waxman statutory and regulatory framework and within the power of the FDA to grant.<sup>12</sup>

Federal regulations provide a 150-day period for the FDA to respond to each petition, subject to some exceptions.<sup>13</sup> Reviewing and responding to these petitions is often a resource-

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<sup>10</sup> Compl. ¶¶ 58-59.

<sup>11</sup> Compl. ¶¶ 59-60.

<sup>12</sup> Compl. ¶¶ 62-63; 21 C.F.R. § 10.30.

<sup>13</sup> See Compl. ¶ 64. From September 2007 until July 2012, the FDA had up to 180 days to respond to a petition. Section 1135 of the Food and Drug Administration Safety and Innovation Act reduced that time period to 150 days in July 2012. See 21 U.S.C. § 355(q)(1)(F), as modified by P.L. 112-144, 126 Stat. 1123, July 9, 2012 .

intensive and time-consuming task requiring the FDA, in addition to its already-existing workload. The FDA's final ruling on a petition constitutes final agency action and can be appealed in court; if for only that reason, the FDA aims to have a complete administrative record reflecting that its decision is based on sound science.<sup>14</sup>

Throughout the 2000s, it was well-known that the FDA's practice was to (1) consider and respond to a petition before approving an ANDA for the generic product that was the subject of the petition and (2) delay approval of the ANDA pending a response to the petition, particularly when the petition was filed by a brand drug manufacturer and claimed to raise (whether correctly or not) a public health or safety concern.<sup>15</sup> Although Congress indicated in 2007 that the FDA may not delay approval of an ANDA application because of any request to take any form of action related to the pending ANDA unless "a delay is necessary to protect the public health,"<sup>16</sup> Congress did not provide the FDA with significant additional resources to address such petitions. Brand drug manufacturers can thus still delay generic approval while the FDA considers whether the petition implicates issues of public health — regardless of whether it is a sham or not. And in the high-stakes world of prescription drugs, even short delays of a few days or weeks can cost purchasers millions of dollars in artificially inflated prices.<sup>17</sup>

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<sup>14</sup> Compl. ¶ 65.

<sup>15</sup> 21 C.F.R. §10.30(e)(2); Compl. ¶ 71.

<sup>16</sup> 21 U.S.C. § 355(q)(1)(A).

<sup>17</sup> Compl. ¶ 72.

**B. Reckitt engaged in a multi-year, multi-faceted, anticompetitive scheme to unlawfully obstruct and delay generic competition for Suboxone.**

**1. Reckitt successfully and safely sold Suboxone tablets for years but developed Suboxone film to forestall generic competition.**

In 2002, Reckitt received FDA approval to sell Suboxone, a buprenorphine hydrochloride and naloxone product indicated for maintenance treatment of opioid (*e.g.*, heroin) addiction.<sup>18</sup> Suboxone changed the treatment of opioid dependence. Prior to 2002, to mitigate the risk of abuse associated with prescribing methadone to opioid-addicted patients, approved opioid dependence treatments could only be dispensed in clinics specializing in addiction treatment.<sup>19</sup> But many opioid-addicted patients avoid such clinics due to privacy concerns and the perceived stigma attached to those programs.<sup>20</sup> Unlike methadone, Suboxone has a built-in abuse-deterrent property: because it is co-formulated with the opioid antagonist naloxone, Suboxone causes the immediate onset of withdrawal symptoms if the drug is inappropriately melted and injected.<sup>21</sup> Because of this, Suboxone was the first drug for the treatment of opioid dependence that could be prescribed in an office setting.<sup>22</sup> Sold in tablet form, Suboxone had no existing patent protection, but the FDA granted Reckitt seven years of regulatory exclusivity from generic competition, lasting until October 2009.<sup>23</sup> Reckitt sold the tablets in child-resistant bottles for

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<sup>18</sup> Compl. ¶¶ 1, 5, 77.

<sup>19</sup> Compl. ¶¶ 5, 75.

<sup>20</sup> Compl. ¶ 76.

<sup>21</sup> Compl. ¶ 5.

<sup>22</sup> Compl. ¶ 5. Reckitt also manufactures Subutex, which is indicated for the brief induction phase of treatment of opioid dependence, as opposed to Suboxone's use as maintenance treatment. Subutex was also approved for office-setting dispensal but as a straight buprenorphine product (rather than a co-formulation with naloxone), it does not have the same abuse-deterrent property as Suboxone. *Id.* ¶¶ 5, 77, 160.

<sup>23</sup> Compl. ¶¶ 6-7, 79. Reckitt achieved these seven years of exclusivity by applying for and receiving an "orphan drug" designation for Suboxone on the grounds, Reckitt argued, that it had no reasonable

*cont'd...*

years without suggesting there were safety issues, and Suboxone quickly became a blockbuster drug, reaching a billion dollars in sales per year.<sup>24</sup>

Knowing that regulatory exclusivity for Suboxone tablets would expire in 2009 and manufacturers of generic products were likely to enter the market soon thereafter, Reckitt hatched and implemented an anticompetitive scheme to delay and hinder competition from less expensive AB-rated generic versions of Suboxone tablets. Reckitt's first step was to develop and obtain FDA regulatory approval for Suboxone film, a different dosage form of Suboxone.<sup>25</sup> Reckitt filed an NDA for Suboxone film in October 2008 and received FDA approval in September 2010.<sup>26</sup> In the meantime, Actavis, Inc. (a generic manufacturer) filed an ANDA for generic Suboxone tablets in 2009.<sup>27</sup>

Suboxone film and Suboxone tablets are, in Reckitt's own words, "comparable according to [pharmacokinetic] parameters and equivalent in effectiveness for treating opioid dependence."<sup>28</sup> That is not surprising, as the two formulations contain the same active ingredients (buprenorphine hydrochloride and naloxone), and Reckitt's NDA for Suboxone film, as the FDA stated, "include[d] no new efficacy studies," but instead relied on the same studies that Suboxone tablets relied upon.<sup>29</sup> The FDA concluded that Reckitt's safety study for Suboxone film was "not useful for demonstrating any difference in the safety profile or abuse

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expectation of recovering its costs for developing and manufacturing the drug, given the low prevalence of the targeted indication — treatment of opioid addiction. *Id.* at ¶¶ 7, 79.

<sup>24</sup> Compl. ¶ 5.

<sup>25</sup> Compl. ¶ 81.

<sup>26</sup> Compl. ¶ 81.

<sup>27</sup> Compl. ¶ 98.

<sup>28</sup> Compl. ¶ 82.

<sup>29</sup> Compl. ¶ 82.

potential of the two formulations,” and thus “it would be impossible to claim any potential advantages of Suboxone [film] over the Suboxone tablet product.”<sup>30</sup>

While equally efficacious, Suboxone film and Suboxone tablets differed in two important ways. First, Suboxone film potentially has safety risks — particularly for children — that Suboxone tablets do not. As the FDA stated, “it should be noted that the proposed filmstrip product cannot be spit out easily and dissolves quickly. Therefore, to the extent that some cases may be mitigated by the child spitting out the tablet before full absorption, the filmstrip product could be more hazardous than the tablet.”<sup>31</sup> Reckitt also attempted to distinguish the film version from the tablet by putting film in unit-dose (individually sealed) packaging, but the FDA found such packaging did not “provide[] meaningful incremental protection against pediatric exposure” or otherwise make Suboxone film safer.<sup>32</sup>

Second, Suboxone film and tablets, true to their names, differ in dosage form. Consequently, while a pharmacist can substitute lower-priced generic Suboxone tablets when presented with a prescription for Suboxone tablets, she cannot do so when presented with a prescription for Suboxone film.<sup>33</sup>

**2. Upon approval of Suboxone film, Reckitt systematically destroyed the market and delayed competition for Suboxone tablets.**

**a. Reckitt vilified its own product to push physicians to prescribe Suboxone film.**

As soon as the FDA approved Suboxone film in the fall of 2010, Reckitt began a sales and marketing campaign to convert prescriptions from Suboxone tablets to Suboxone film before

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<sup>30</sup> Compl. ¶ 83.

<sup>31</sup> Compl. ¶ 84. The FDA also noted that the film version is easier to conceal, dissolve, and inject, leading to “significant abuse and diversion.” *Id.* at ¶ 85.

<sup>32</sup> Compl. ¶ 86.

<sup>33</sup> Compl. ¶ 88.

generic versions of Suboxone tablets could be approved.<sup>34</sup> Reckitt raised the prices of Suboxone tablets relative to Suboxone film (despite the fact that the film was more expensive to manufacture and package) and disparaged the tablet formulation to physicians on the pretext of alleged safety concerns.<sup>35</sup> Reckitt misleadingly told physicians the supposed safety concerns raised by Suboxone tablets had been overcome by Suboxone film and that the company was going to stop selling Suboxone tablets; according to Reckitt, physicians need not stop prescribing Suboxone at all but should simply prescribe the film.<sup>36</sup> Reckitt admitted to investors that the switch strategy was implemented to “help mitigate the impact” that generic versions of Suboxone tablets would have on its revenues.<sup>37</sup>

But Reckitt’s massive marketing campaign touting Suboxone film over Suboxone tablets was based on false premises and pretexts: (a) that Suboxone tablets carried safety risks and (b) Suboxone film, because it was sold in unit-dose packaging, overcame those risks. First, the FDA found (and Reckitt knew) that Suboxone film was neither safer nor more effective than Suboxone tablets (and Reckitt had no studies to demonstrate otherwise).<sup>38</sup> Second, the FDA found (and Reckitt knew) that the unit-dose packaging for Suboxone film did not “provide[] meaningful incremental protection against pediatric exposure.”<sup>39</sup> Even assuming unit-dose packaging provided some incremental advantage over normal storage bottles (which it does not), Reckitt long ago could have implemented unit-dose packaging for Suboxone tablets: it admitted

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<sup>34</sup> Compl. ¶¶ 89-92.

<sup>35</sup> Compl. ¶¶ 89-90.

<sup>36</sup> Compl. ¶¶ 10, 89, 93.

<sup>37</sup> Compl. ¶ 91.

<sup>38</sup> Compl. ¶ 83.

<sup>39</sup> Compl. ¶ 86.

to the FDA that such packaging was “feasible” and had sold Suboxone tablets with such packaging in Canada and the European Union for years.<sup>40</sup>

In September 2012, Reckitt publicly announced that it would stop selling Suboxone tablets, citing the false safety risks.<sup>41</sup> This announcement helped push physicians to prescribe Suboxone film, believing they would have no alternative soon.<sup>42</sup> But while announcing its intent to stop selling in September 2012, Reckitt continued selling these supposedly dangerous Suboxone tablets until March 2013 — just as generic Suboxone tablets entered the market.<sup>43</sup>

Reckitt’s anticompetitive product hopping scheme was highly successful: by the end of 2012, nearly 70% of Suboxone prescriptions were for Suboxone film.<sup>44</sup>

**b. Reckitt feigned cooperation with generic manufacturers working on a shared REMS program but instead simply impeded the process to delay competition.**

Reckitt also worked to forestall entry of AB-rated generic Suboxone tablets, for the longer an AB-rated generic stayed off of the market, the more time Reckitt had to destroy the market for Suboxone tablets, leaving the impending generic Suboxone tablets with virtually nothing pharmacists could automatically substitute them for.

The FDA required Reckitt to adopt a REMS program for Suboxone to address pediatric exposure concerns, and approved a REMS for the film in 2010 and the tablets in December

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<sup>40</sup> Compl. ¶ 87.

<sup>41</sup> Compl. ¶ 93.

<sup>42</sup> Compl. ¶ 93.

<sup>43</sup> Compl. ¶ 94.

<sup>44</sup> Compl. ¶ 92.

2011.<sup>45</sup> The FDA did not require any changes in packaging for Suboxone tablets, and instead approved a REMS that addressed safety concerns through FDA-approved labeling.<sup>46</sup>

By the time of Reckitt's tablet REMS approval in December 2011, two manufacturers — Actavis and Amneal — had ANDAs pending before the FDA for generic Suboxone tablets.<sup>47</sup> The FDA immediately informed Actavis and Amneal that all Suboxone products would be subject to a Single Shared REMS program ("SSRS"), advised them to collaborate with Reckitt on this project, and mandated compliance by May 6, 2012.<sup>48</sup> The SSRS was a precondition to approval of ANDAs for generic Suboxone tablets, but the generics would need access to Reckitt's information about its REMS program to effectuate the SSRS; as such, the generics promptly contacted Reckitt and proceeded in good faith and with all due urgency to complete this process to receive final approval of their ANDAs.<sup>49</sup>

Reckitt promised but feigned cooperation for months, throwing up numerous procedural and substantive roadblocks but never informing the generic ANDA filers or the FDA that it had no intention of sharing its own data for completion of the SSRS.<sup>50</sup> In June 2012, after being contacted by the generic manufacturers to discuss the delays caused by Reckitt, the FDA informed Reckitt and the generic manufacturers that they should develop a new SSRS based on the FDA's initial REMS notification letter to Reckitt, without using any of Reckitt's existing information.<sup>51</sup> Reckitt refused to share its information and the FDA could not compel it to do so,

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<sup>45</sup> Compl. ¶¶ 95, 99.

<sup>46</sup> Compl. ¶ 99.

<sup>47</sup> Compl. ¶ 98.

<sup>48</sup> Compl. ¶¶ 100-01.

<sup>49</sup> Compl. ¶¶ 102-03.

<sup>50</sup> Compl. ¶¶ 105-10.

<sup>51</sup> Compl. ¶¶ 107-08.

though the FDA did remind Reckitt that “actions designed to ‘block or delay’ approval of [the generics’] ANDAs, or otherwise preventing the application of an SSRS to an ANDA drug, were prohibited” by law.<sup>52</sup>

Reckitt advised the FDA that it would cooperate with the generic sponsors to develop this new SSRS, but instead it continued to delay the process.<sup>53</sup> Among other things, Reckitt demanded “veto authority or a super-majority vote for all issues relating to administration of the SSRS” and that each filer of an ANDA for generic Suboxone “agree to share a pre-specified percentage of all product liability claims, regardless of fault,” an unheard-of term for an SSRS.<sup>54</sup> And in mid-August 2012, just hours before finalization of the draft new SSRS to be submitted to FDA, Reckitt again concocted last minute obstacles and refused to submit the SSRS with its NDA filing.<sup>55</sup>

On October 3, 2012, recognizing Reckitt had strategically delayed the SSRS process for nearly ten months, Actavis and Amneal filed a waiver request with the FDA to seek approval of a generics-only SSRS.<sup>56</sup> Had Reckitt not improperly misused the SSRS process as a means for delay, Actavis and Amneal could and would have more quickly sought and obtained approval of the generics-only SSRS that they ultimately used, resulting in earlier approval of their ANDAs, the launch of less-expensive AB-rated versions of Suboxone tablets, and savings for purchasers.<sup>57</sup>

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<sup>52</sup> Compl. ¶ 108. *See also id.* ¶ 60.

<sup>53</sup> Compl. ¶¶ 109-11.

<sup>54</sup> Compl. ¶ 109. As the generic filers pointed out to the FDA, “other SSRS programs have standard cross-indemnification provisions for fault-based claims” and the upfront agreement Reckitt sought “would deprive [the generic manufacturers] of coverage under their product liability insurance policies.” *Id.*

<sup>55</sup> Compl. ¶ 110.

<sup>56</sup> Compl. ¶ 112.

<sup>57</sup> Compl. ¶¶ 153, 155.

**c. Reckitt filed a meritless sham petition to perpetuate its unlawful monopoly.**

Reckitt piggy-backed another delay tactic onto its SSRS foot-dragging: on September 25, 2012, as Actavis and Amneal were set to file their generics-only SSRS request with the FDA, Reckitt both (1) formally announced its intent to permanently withdraw Suboxone tablets from the U.S. market for safety reasons, and (2) filed a petition requesting that the FDA delay approval of generic Suboxone tablet ANDAs.<sup>58</sup> The petition to the FDA purported to raise safety issues with generic versions of Suboxone tablets, and requested that the FDA not approve an ANDA (1) unless it included both a targeted pediatric exposure education program and unit-dose packaging and (2) until the FDA determined whether Reckitt's branded Suboxone tablets had been discontinued for safety reasons.<sup>59</sup>

None of these requests had merit, and Reckitt had no reasonable expectation of success. The petition was instead a sham, filed solely to delay ANDA approval and entry of generic competition for Suboxone tablets, and to artificially extend Reckitt's Suboxone monopoly.<sup>60</sup>

First, the FDA had no authority to grant Reckitt's request that ANDAs for generic Suboxone include a targeted pediatric exposure education program.<sup>61</sup> As a matter of law, the FDA could only require ANDA filers to mimic the FDA-approved REMS and labeling for Suboxone. Although Reckitt had a voluntary educational program, such program was neither part of the REMS nor part of the labeling for Suboxone; as such, Reckitt knew the FDA could not require that ANDA filers adopt it.<sup>62</sup>

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<sup>58</sup> Compl. ¶ 113.

<sup>59</sup> Compl. ¶¶ 115, 121-23.

<sup>60</sup> Compl. ¶ 114.

<sup>61</sup> Compl. ¶ 116.

<sup>62</sup> Compl. ¶¶ 117-19.

Second, Reckitt's own business practices betrayed the baselessness of its requests. Although Reckitt requested that the FDA require generic Suboxone tablets to come in unit-dose packaging, Reckitt continued to sell branded Suboxone tablets in child-resistant bottles, just as the company had for the prior decade despite the risk of pediatric exposure.<sup>63</sup> More importantly for the FDA's purposes, Reckitt provided no well-controlled, statistically significant scientific support for its proposition that Suboxone film in unit-dose packaging was safer — and the FDA can only act on such support.<sup>64</sup>

Third, despite Reckitt's claims that the tablets were unsafe, it had not actually stopped selling Suboxone tablets when it filed the petition, and despite its earlier threats to physicians that it would do so, Reckitt would not stop until March 2013, as Actavis and Amneal entered the market with generic Suboxone tablets.<sup>65</sup> But even if the request had been ripe for adjudication by the FDA, it was still baseless, since (1) Reckitt had successfully sold Suboxone tablets in bottles for ten years, (2) the child-resistant bottles were and had been safe and effective, (3) the FDA did not believe that unit-dose packaging was superior but did believe the REMS and approved labeling were adequate to reduce the risk of pediatric exposure, and (4) Reckitt had presented no clinically significant studies demonstrating that Suboxone tablets (themselves or as sold in child-resistant bottles) were unsafe.<sup>66</sup>

Had Reckitt been genuinely concerned about significant safety issues associated with Suboxone tablets, it would have (1) introduced Suboxone tablets long ago in unit-dose packaging as it had done in Canada and the European Union (and admitted was feasible in the United

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<sup>63</sup> Compl. ¶¶ 124-25.

<sup>64</sup> Compl. ¶ 130.

<sup>65</sup> Compl. ¶¶ 143-44.

<sup>66</sup> Compl. ¶¶ 122-23.

States) or (2) removed the tablets and filed this type of petition years earlier.<sup>67</sup> Instead, Reckitt strategically delayed filing its petition until the eve of approval of ANDAs for generic Suboxone tablets, just when Actavis and Amneal finally gave up trying to negotiate a joint REMS with Reckitt and sought a generics-only REMS protocol with FDA.<sup>68</sup> All the while, Reckitt took advantage of the delay, running the clock and continuing to convert prescriptions from Suboxone tablets to Suboxone film based on false claims of film superiority and safety to frustrate and limit eventual generic competition.

On February 20, 2013, the FDA denied Reckitt's petition in full, citing Reckitt's lack of evidentiary support, and referred the matter to the FTC for an antitrust investigation.<sup>69</sup> On that same day, the FDA granted final approval to Actavis and Amneal for the sale and marketing of their AB-rated generic versions of Suboxone tablets, and these generics promptly entered the market — or what was left of it after Reckitt's switch to film.<sup>70</sup> As a last ditch effort to block generic substitution, Reckitt pulled its tablet version from the market, despite the FDA's conclusion that Reckitt had not done so (or was not doing so) due to legitimate safety issues.

### **LEGAL STANDARD**

Rule 8 of the Federal Rules of Civil Procedure requires only a “short and plain statement of the claim showing that the pleader is entitled to relief.”<sup>71</sup> “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is

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<sup>67</sup> Compl. ¶ 133.

<sup>68</sup> Compl. ¶ 136.

<sup>69</sup> Compl. ¶¶ 141-43.

<sup>70</sup> Compl. ¶¶ 143-44.

<sup>71</sup> Fed. R. Civ. P. 8(a)(2).

plausible on its face.’”<sup>72</sup> The plaintiff satisfies this standard when it “pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”<sup>73</sup> This analysis, as this Court has acknowledged, is “‘context-specific’ and requires the court to draw on ‘its judicial experience and common sense’ to determine if the facts pled in the complaint have ‘nudged [plaintiff’s] claims’ over the line from ‘[merely] conceivable [or possible] to plausible.’”<sup>74</sup>

To state an antitrust claim under Section 2 of the Sherman Act, a plaintiff must plead facts indicating: “(1) the possession of monopoly power in the relevant market; and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”<sup>75</sup> The Third Circuit discourages dismissals of antitrust claims at the pleading stage.<sup>76</sup>

## ARGUMENT

### A. **Antitrust law prohibits Reckitt’s “product hopping scheme” to unlawfully thwart generic competition.**

Product hopping schemes violate federal antitrust laws. The hallmarks of an anticompetitive product hop are: (1) a brand drug company introduces a “new” product that offers trivial or no substantive improvements over an existing drug product; (2) the original formulation is on the cusp of having competition from an AB-rated generic version; and (3) the

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<sup>72</sup> *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 550 (2007)). See also *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) (citation omitted).

<sup>73</sup> *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 550).

<sup>74</sup> *Suber v. Guinta*, 902 F. Supp.2d 591, 600 (E.D. Pa. 2012) (citing *Iqbal*, 556 U.S. at 679-80).

<sup>75</sup> *Schuylkill Energy Res., Inc. v. Pa. Power & Light Co.*, 113 F.3d 405, 412-13 (3d Cir. 1997) (quoting *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 197 (3d Cir. 1992)).

<sup>76</sup> See, e.g. *Brader v. Allegheny Gen. Hosp.*, 64 F.3d 869, 876 (3d Cir. 1995); see also *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 425 U.S. 738, 746 (1976) (holding that in antitrust cases, where “proof is largely in the hands of the alleged conspirators, dismissals prior to giving the plaintiff ample opportunity for discovery should be granted very sparingly”).

brand manufacturer destroys the prior formulation's prescription base by converting the vast majority of the old formulation's users to the new, non AB-rated version prior to entry by the AB-rated generic, either by falsely disparaging the original formulation, announcing its withdrawal or discontinuance, or both. By taking these actions, the brand drug company intentionally disrupts the automatic generic substitution mechanism designed by the Hatch-Waxman Act and state generic substitution laws to foster price competition between brand and AB-rated generic drugs and, in turn, lower prices for the drug at issue. By the time AB-rated generic versions of the original formulation come to market after an impermissible product hop, few patients still hold prescriptions for the original formulation of the drug, and pharmacists cannot automatically substitute the less-expensive generic formulation for the prescription for the new formulation presented to them.

**1. Courts recognize that brand drug product hopping schemes unlawfully restrict competition and cause antitrust injury.**

The Supreme Court observed in *Verizon Commc'ns, Inc. v. Law Offices of Curtis V. Trinko, LLP* that “[a]ntitrust analysis must always be attuned to the particular structure and circumstances of the industry in question.”<sup>77</sup> Brand drug product hopping requires particular antitrust scrutiny because a generic substitute can, as a practical matter, compete only on price.<sup>78</sup> In efficient markets, price plays an important role in product selection because the person selecting the product also pays for the product. In the drug marketplace, however, the person

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<sup>77</sup> 540 U.S. 398, 411 (2004) (“*Trinko*”).

<sup>78</sup> Hatch-Waxman treats generic products as commodities that cannot be differentiated through marketing except on price.

selecting the product – the doctor – does not pay for the product.<sup>79</sup> Thus, there is a “price disconnect” that prevents the marketplace from functioning efficiently.<sup>80</sup>

Brand drug manufacturers such as Reckitt exploit this inherent market characteristic by promoting their brand products primarily to doctors, without reference to price.<sup>81</sup> Generic companies return price to the equation by offering low prices to wholesalers and pharmacies, and distributing their products, without promotion, through the automatic substitution laws applicable to AB-rated generics.<sup>82</sup> This, as Hatch-Waxman envisions, is how generic prices are low — generic manufacturers do not have to spend enormous funds to market their products and pass those savings on to purchasers. Hatch-Waxman “speed[s] the introduction of low-cost generic drugs to market”<sup>83</sup> and state generic substitution laws “foster price competition by allowing the only principals who have financial incentives to make price comparisons — the pharmacist and the patient — to select drug products on the basis of price.”<sup>84</sup>

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<sup>79</sup> Compl. ¶¶ 45-47.

<sup>80</sup> Compl. ¶¶ 46-47. *See also* Drug Product Selection, Staff Report to the FTC (Jan. 1979) [“FTC Staff Report”] at 2-3 (“the forces of competition do not work well in a market where the consumer who pays does not choose, and the physician who chooses does not pay. Patients have little influence in determining which products they will buy and what prices they must pay for prescriptions”) (available at <http://catalog.hathitrust.org/Record/000258518>); *see also* A. Masson and R. Steiner, *GENERIC SUBSTITUTION AND PRESCRIPTION DRUG PRICES: ECONOMIC EFFECTS OF STATE DRUG PRODUCT SELECTION LAWS* (FTC 1985) at 5 [“Generic Substitution”] (“the institutions of the prescription drug market are markedly different from those in most other product markets. For prescription drugs, it has not been the consumer who has made the choice among brands; it has been the physician”) (available at <http://catalog.hathitrust.org/Record/002589428>).

<sup>81</sup> Compl. ¶ 47; *see also* FTC Staff Report at 35-36 (heavy detailing reinforces “doctors’ brand-name prescribing habits,” extends brand dominance “long after patents have expired,” and “reduces the degree of substitutability between products,” allowing higher prices).

<sup>82</sup> Compl. ¶¶ 48-49.

<sup>83</sup> *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012).

<sup>84</sup> FTC Staff Report at 7.

Product hopping schemes such as the one alleged here are clearly actionable.<sup>85</sup> In similar litigation involving the brand prescription drug TriCor, Judge Kent Jordan (now a judge of the Court of Appeals of this Circuit) rejected the defendants' arguments, no different than those Reckitt makes here, that product changes are generally *per se* legal "innovations" immunized by antitrust law.<sup>86</sup> Given FDA regulations governing generic drug approval and automatic pharmacy substitution, and the ability of drug manufacturers to "game" them, Judge Jordan ruled that "the effect of Defendants' formulation changes" should, like most antitrust claims, be evaluated under a rule-of-reason approach:

Contrary to Defendants' assertion, Plaintiffs are not required to prove that the new formulations were absolutely no better than the prior version or that the only purpose of the innovation was to eliminate the complementary product of a rival. Rather, as in *Microsoft*, if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants.<sup>87</sup>

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<sup>85</sup> See *Mylan v. Warner Chilcott*, Case No. 12-3824, ECF No. 280 (E.D. Pa. June 12, 2013) (denying motion to dismiss product hop claim involving the drug Doryx); *Abbott Labs. v. Teva Pharms. USA, Inc.*, 432 F. Supp.2d 408 (D. Del. 2006) (denying Rule 12 motion in product hop claim) ("*TriCor*"); *TriCor*, Case No. 05-340, Mem. Ord., ECF No. 434 (D. Del. Aug. 18, 2008) (denying Rule 56 motion in product hop claim). Numerous other decisions where product changes were held actionable are discussed below.

<sup>86</sup> Abbott, the brand drug company in *TriCor*, employed a product hopping scheme very similar to that employed here — with similar anticompetitive effect. Abbott switched the market first from a capsule formulation to a tablet formulation with a different milligram strength, and then hopped to yet another milligram strength. As Reckitt did here, Abbott obtained approval for these "new" versions by showing they were clinically equivalent to the prior versions, not clinically superior. Plaintiffs there, as here, alleged that while the new formulations were clinically equivalent to the prior formulations, they were not AB-rated (and thus patients could not benefit from automatic generic substitution). As planned, defendants shifted the focus of their marketing from the prior formulation to their new formulations, minimizing the number of prescriptions of the prior formulations before generic versions of the prior formulations were approved. The case settled after the commencement of trial.

<sup>87</sup> *TriCor*, 432 F. Supp. 2d at 422 (citing *U.S. v. Microsoft Corp.*, 253 F.3d 34 (D.C. Cir. 2001)). The Court may not consider Reckitt's asserted procompetitive justifications on a motion to dismiss. See *Advanced Health-Care Servs. v. Radford Cmty. Hosp.*, 910 F.2d 139, 145 (4th Cir. 1990) (on motion to dismiss, court must accept plaintiffs' allegations of adverse effects on competition as true and must consider defendants' pro-competitive justifications as unproven); *In re K-Dur Antitrust Litig.*, 338 F. Supp. 2d 517, 533 (D.N.J. 2004) (same); *Balaco, Inc. v. Upjohn Co.*, 1992 WL 131150, at \*2 (E.D. Pa. 1992) (defendants' position on "pro-competitive effect is not relevant at this stage in the litigation. . . . a factual determination of the actual competitive effects is not appropriate on a motion to dismiss").

*TriCor* finds roots in precedent from the Courts of Appeal such as *C.R. Bard v. M3 Systems*,<sup>88</sup> *Berkey Photo, Inc. v. Eastman Kodak Company*,<sup>89</sup> and especially *U.S. v. Microsoft Corp.*<sup>90</sup> Judge Jordan held in *TriCor* that by impeding its generic competitors' access to the cost-efficient means of distribution (*i.e.*, automatic pharmacy substitution), a brand drug manufacturer can illegally maintain its monopoly.<sup>91</sup> *TriCor* is on-point authority here.

*C.R. Bard* is to the same effect. There, plaintiffs challenged Bard's scheme to exclude competitors by, among other things, modifying its device to raise competitors' costs and impede doctors' use of "copycat" needles. Bard defended by arguing that its product changes were improvements. The Federal Circuit upheld a jury verdict in plaintiffs' favor, finding that "the jury could reasonably conclude that Bard's modifications to its [needle] guns constituted 'restrictive or exclusionary conduct' in a market over which it had monopoly power."<sup>92</sup> *C.R.*

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<sup>88</sup> 157 F.3d 1340 (Fed. Cir. 1998).

<sup>89</sup> 603 F.2d 263 (2d Cir. 1979).

<sup>90</sup> See *Microsoft Corp.*, 253 F.3d at 65 ("[j]udicial deference to product innovation, however, does not mean that a monopolist's product design decisions are per se lawful"). A long line of precedent refutes entirely Reckitt's claim that product changes are immune from antitrust scrutiny. *E.g.*, *Ne. Tel. Co. v. AT&T*, 651 F.2d 76 (2d Cir. 1981) (remanding Section 2 claim for trial where the sole remaining allegation of anticompetitive conduct was the design change); *Foremost Pro Color, Inc. v. Eastman Kodak Co.*, 703 F.2d 534, 545 (9th Cir. 1983) ("We do not, of course, hold that product innovation is immune from antitrust scrutiny and may never provide the requisite conduct element in support of a claim for monopolization or attempted monopolization under section 2 of the Sherman Act"); *Multistate Legal Studies, Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 63 F.3d 1540, 1551-52 & nn.9-10 (10th Cir. 1995); *Xerox Corp. v. Media Scis. Int'l, Inc.*, 511 F. Supp. 2d 372, 387 (S.D.N.Y. 2007) ("several courts have found that product redesign, when it suppresses competition and is without other justification, can be violative of the antitrust laws") (citing *Microsoft*, 253 F.3d at 65-67); *In re IBM Peripheral EDP Device Antitrust Litig.*, 481 F. Supp. 965, 1003 (N.D. Cal. 1979) ("[i]t is not difficult to imagine situations where a monopolist could utilize the design of its own product to maintain market control or to gain competitive advantage . . . if those [] changes had no purpose and effect other than the preclusion of [competitors], this Court would not hesitate to find that such conduct was predatory [and] . . . that use of monopoly power would be condemned"), *aff'd sub nom. Transam. Computer Co., Inc. v. IBM Corp.*, 698 F.2d 1377 (9th Cir. 1983).

<sup>91</sup> 432 F.Supp.2d at 423 (citing *Microsoft*, 253 F.2d at 64).

<sup>92</sup> *C.R. Bard*, 157 F.3d at 1382.

*Bard* provides a threshold reason why defendants' motions to dismiss here should be denied: whether Reckitt impeded competition because of an exclusionary scheme or simply instituted improvements to Suboxone by changing the formulations is a question for the jury.<sup>93</sup>

Contrary to Reckitt's bid for immunity under "antitrust injury" principles, product hopping schemes cause the very type of harm that the Third Circuit considers to be quintessential antitrust injury: overcharges paid by direct purchasers for a product, the price of which is inflated by defendant's improper exclusion or suppression of competition.<sup>94</sup> In *Warfarin*, the Third Circuit unambiguously held that impeding generic competition in the drug industry — and thereby minimizing substitution of lower priced generics for their expensive branded counterparts — is exclusionary conduct that inflicts classic antitrust injury (overcharges) on purchasers.<sup>95</sup> In *Warfarin*, the effect "was to raise Barr Laboratories' cost to enter the [generic]

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<sup>93</sup> Reckitt relies on *Berkey Photo* and *Medtronic Minimed, Inc. v. Smiths Med. MD, Inc.*, 371 F.Supp.2d 578 (D.Del. 2005) in arguing that courts are reluctant to weigh in on whether a new product design is exclusionary. But the *Berkey Photo* court's reluctance, as Judge Jordan recognized in *TriCor*, was based on its conclusion that the anticompetitive effects resulted from consumers' free choice, not the defendants' conduct. "Consumers who are free to choose among various products enjoy the presence of competition rather than its absence." *TriCor*, 432 F. Supp. 2d. at 423. "In the absence of free consumer choice, the basis for judicial deference is removed" and a product design change used as coercive means of extending market power is actionable. *Id.* Here, the plaintiffs allege that the market shift to film was the result of just such coercive and predatory tactics. See Compl. ¶¶ 10, 81-97. In *Medtronic*, the Court noted that there were no significant barriers to competitive entry (*Medtronic*, 371 F. Supp. 2d at 587); whereas there are significant barriers to generic entry here (Compl. ¶¶ 10-13, 56, 162). Moreover, the *Medtronic* plaintiff did not contend that it was hindered from marketing the new design; did not contend it had lost any sales as a result of the design; could have sold compatible products if it chose to do so; and was not "foreclose[d from] the market in any meaningful way." *Medtronic*, 371 F. Supp. 2d at 587, *see also id.* at 583-87. It was for those reasons that Judge Robinson — who denied summary judgment in *TriCor* after Judge Jordan was elevated to the Third Circuit — granted summary judgment to the *Medtronic* defendant. *Id.* at 588-89. Also, contrary to Reckitt's suggestion, the Ninth Circuit in *Allied Orthopedic Appliances, Inc. v. Tyco Health Care Group LP* did not immunize product changes. On the contrary, the court there held that "changes in product design are *not* immune from antitrust scrutiny and in certain cases may constitute an unlawful means of maintaining a monopoly under Section 2." *Allied Orthopedic*, 592 F.3d 992, 998 (9th Cir. 2010) (emphasis added).

<sup>94</sup> *In re Warfarin Antitrust Litig.*, 214 F.3d 397, 401 (3d Cir. 2000).

<sup>95</sup> *Id.*

market and to disable its market penetration.”<sup>96</sup> Where, as here, such a scheme succeeds, “[i]t is difficult to imagine a more formidable demonstration of antitrust injury.”<sup>97</sup>

In *TriCor*, Judge Jordan held that defendants’ alleged conduct could have blocked competition and formed the basis of a claim — that is, it caused cognizable antitrust injury.<sup>98</sup> The *TriCor* defendants argued that because the generics “had not been prevented from marketing the formulations that were the subject of their ANDAs, *i.e.*, the old TriCor formulations, they were not completely foreclosed, and were free to compete.”<sup>99</sup> In rejecting the argument, Judge Jordan explained that to show that conduct has an anticompetitive effect, “it is not necessary that all competition be removed from the market. *The test is not total foreclosure*, but whether the challenged practices bar a substantial number of rivals or severely restrict the market’s ambit.”<sup>100</sup> As in *TriCor*, Reckitt’s product hop “severely restricted the ambit” of generic competition by limiting the number of prescriptions that could be subject to automatic AB-rated generic substitution. Schemes that foreclose lower priced competitors from the market, thereby allowing

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<sup>96</sup> *Id.* at 397.

<sup>97</sup> 214 F.3d at 401. *See also In re Cardizem CD Antitrust Litig.*, 332 F.3d 896, 910 (6th Cir. 2003) (“[p]reventing that kind of injury [an overcharge] was undoubtedly a *raison d’être* of the Sherman Act when it was enacted in 1890”). By the same reasoning, this Court should reject Reckitt’s argument that the direct purchaser plaintiffs have failed to plead antitrust injury. The Complaint alleges that, by decreasing competition in the market for Suboxone, the overall intent and effect of Reckitt’s scheme was to forestall generic competition, thereby causing plaintiffs to pay more for co-formulated buprenorphine/naloxone products than they otherwise would have paid. Compl. ¶¶ 4, 14, 97. This is precisely the type of injury that the antitrust laws were intended to prevent and clearly satisfies the requirements of Section 4 of the Clayton Act. *See Brunswick Corp. v. Pueblo Bowl-O-Mat*, 429 U.S. 477, 489 (1977) (antitrust injury is that which flows from decreased competition); *In re Warfarin*, 214 F.3d at 401.

<sup>98</sup> *TriCor*, 432 F. Supp. 2d at 423.

<sup>99</sup> *Id.* (“Defendants are correct that, according to Plaintiffs’ allegations, Teva and Impax have not been prevented from marketing the formulations that were the subject of their ANDAs, *i.e.*, the old TriCor formulations”).

<sup>100</sup> *Id.* at 422-23 (citing *U.S. v. Dentsply Int’l, Inc.*, 399 F.3d 181, 191 (3d Cir. 2005) and *Microsoft*, 253 F.3d at 65-67) (emphasis added).

a monopolist to impose higher prices on purchasers without losing significant sales, are textbook examples of conduct that can — and must — be carefully scrutinized under Third Circuit law.<sup>101</sup> “When the introduction of a new product by a monopolist prevents consumer choice, greater scrutiny is appropriate.”<sup>102</sup> The direct purchaser plaintiffs claim overcharges from being deprived of less-expensive generic buprenorphine hydrochloride and naloxone products due to a wrongful exercise of monopoly power. Antitrust law provides a remedy precisely for abuses of this type.

## **2. The Complaint alleges that the tablet-to-film product hop was exclusionary.**

The direct purchaser plaintiffs allege: (1) Reckitt introduced a new film formulation of Suboxone that offered no medical benefit over the existing tablet formulation (*i.e.*, the film was no more effective than the tablet) but raised additional safety concerns that were not associated with the tablet; (2) the new film formulation did not have an imminent AB-rated generic version, while the tablet formulation would in short order; and (3) Reckitt substantially destroyed the prescription base for the tablet product through a predatory and coercive marketing scheme that included falsely disparaging the safety profile of Suboxone tablets and falsely claiming that Suboxone film improved that safety profile,<sup>103</sup> announcing an intended discontinuation of the

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<sup>101</sup> *Dentsply*, 399 F.3d at 194.

<sup>102</sup> *TriCor*, 432 F.Supp.2d at 421. The fact that Reckitt is an alleged monopolist is highly significant. “[B]ehavior that otherwise might comply with the antitrust law may be impermissibly exclusionary when practiced by a monopolist.” *Dentsply*, 399 F.3d at 187; *LePage’s*, 324 F.3d at 151-52 (a “monopolist is not free to take certain actions that a company in a competitive . . . market may take”). *See also Microsoft*, 253 F.3d at 65 (“[j]udicial deference to product innovation, however, does not mean that a monopolist’s product design decisions are per se lawful”).

<sup>103</sup> Contrary to Reckitt’s suggestions otherwise, such conduct is cognizable exclusionary conduct under the antitrust laws. *See LePage’s Inc. v. 3M*, 324 F.3d 141, 153 (3d Cir. 2003) (en banc) (“providing misleading information to retailers” is “a good illustration of . . . exclusionary conduct”); *In re Warfarin*, 214 F.3d at 397 (claim that generic entry was impaired by “publication and dissemination of false and misleading information to the public” states claim of antitrust injury); *W. Penn Allegheny Health Sys. v. UPMC*, 627 F.3d 85, 109 (3d Cir. 2010) (“making false statements”); *Caribbean Broad. Sys. Ltd. v.*  
*cont’d...*

tablets based on false claims of safety issues surrounding the tablets and safety superiority of film, and actually discontinuing the tablet product entirely when AB-rated generic versions of Suboxone tablets eventually launched.<sup>104</sup>

The direct purchaser plaintiffs further allege that (1) Reckitt knew that film was neither safer nor more effective than tablets and Reckitt had no studies supporting its claim<sup>105</sup>; (2) FDA specifically informed Reckitt that it did “not agree that the packaging for [Suboxone film] provides meaningful incremental protection against pediatric exposure”<sup>106</sup>; and (3) even assuming unit-dose packaging provided some incremental advantage over normal child-resistant storage bottles (which it does not), there was no need for Reckitt to create a film version in order to implement unit-dose packaging.<sup>107</sup>

Reckitt’s tablet-to-film product change neither offered any (or any meaningful) medical or clinical benefit to consumers over the prior formulation, nor did it boost sales, lower cost, or increase efficiency for defendants. The direct purchaser plaintiffs allege just the opposite: that

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*Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998) (defendants’ anti-competitive conduct consisted of making misrepresentations to advertisers); *Int’l Travel Arran. v. Western Air, Inc.*, 623 F.2d 1255 (8th Cir. 1980) (deceptive advertising campaign must be considered in evaluating claim of anticompetitive scheme). *Santana Prods. Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 608 (3d Cir. 2005), cited by Reckitt at 17-18, is distinguishable, because there, unlike here, the plaintiff did not “allege that Bobrick engaged in coercive measures that prevented Santana from selling its products to any willing buyer or prevented others from dealing with Santana.” *Id.* at 132. Moreover, the Third Circuit subsequently limited its dictum in *Santana Prods.* on which Reckitt relies, explaining that it had spoken in “overly broad terms.” *See W. Penn*, 627 F.3d 85, 109 n.14 (3d Cir. 2010).

<sup>104</sup> Compl. ¶¶ 4, 10-13, 82-86, 89-90, 93, 96-98, 113-14, 131, 144-46, 149, 151-52, 168, 174. Reckitt is not new to such product hopping allegations; in 2011 Reckitt was found to have engaged in anti-competitive product hopping behavior regarding Gaviscon. *See* End-Payor Complaint ¶¶ 83-87 (ECF No. 48).

<sup>105</sup> Compl. ¶¶ 82-86.

<sup>106</sup> Compl. ¶ 131.

<sup>107</sup> Compl. ¶¶ 132-36. Reckitt has sold Suboxone Tablets in unit-dose packaging in countries such as Canada and the EU for years and admitted to the FDA that selling Suboxone Tablets in unit-dose packaging in the U.S. was “feasible.” *Id.* at ¶ 136 and Compl. Ex. E (Amneal letter) at 8 n.13. *See also* Canadian Suboxone Monograph at 22, available at <http://freepdfhosting.com/d721c1d74a.pdf>.

Reckitt's product change was economically irrational, and made sense only because it blocked generic tablet versions of Suboxone.<sup>108</sup> Reckitt merely deprived generic tablet manufacturers (and thus consumers) of the most efficient means of distribution of their generic products and reduced consumer choice by lying to doctors and withdrawing its Suboxone tablets from the market, despite the fact that FDA had confirmed the safety of the tablet.<sup>109</sup>

### 3. Reckitt's efforts to distinguish *TriCor* fail.

*TriCor*, and the solid basis upon which Judge Jordan built his opinion, remain good law, and Reckitt's suggestion that decisions in *Trinko*, *ZF Meritor, LLC v. Eaton Corp.*,<sup>110</sup> or *Pac. Bell Tel. Co. v. Linkline Commc'ns Inc.*<sup>111</sup> have undermined *TriCor* has no merit.<sup>112</sup>

First, *Trinko* predates *TriCor*, and Judge Jordan expressly rejected the defendants' arguments based on *Trinko*. As Reckitt has attempted here, the *TriCor* defendants attempted to

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<sup>108</sup> Compl. ¶152. Reckitt inexplicably asserts that the direct purchaser plaintiffs have not done so (Reckitt Br. at 12, 16-17), but the direct purchaser plaintiffs clearly and specifically allege in ¶ 152 of the Complaint that but for the expected demolition of generic competition, it would not have been economically rational for Reckitt to invest in the process of developing the film product, changing manufacturing processes, obtaining FDA approval, and engaging in significant marketing efforts to switch the market to the new formulation. *Id.* See also *Covad Comm'ns Co. v. Bell Atl. Corp.*, 398 F.3d 666, 676 (D.C. Cir. 2005) ("A 'predatory' practice is one in which a firm sacrifices short-term profits in order to drive out of the market or otherwise discipline a competitor"); see also *Neumann v. Reinforced Earth Co.*, 786 F.2d 424, 427 (D.C. Cir. 1977) (Bork, J.) ("predation involves aggression against business rivals through the use of business practices that would not be considered profit maximizing except for the expectation that . . . actual rivals will be driven from the market, or the entry of potential rivals blocked or delayed, so that the predator will gain or retain a market share sufficient to command monopoly profits").

<sup>109</sup> Compl. ¶¶ 11, 56, 144-46. Any claims by Reckitt that it increased choice in the market are flatly contradicted by the allegations of the Complaint, and therefore, at the very least, create a material issue of fact that cannot be decided at the motion to dismiss stage. See *Motorup Corp. v. Galland, Kharash & Garfinkle, P.C.*, 2001 WL 34368760, \*2 (E.D. Pa. Dec. 4, 2001) ("It is not the duty of the court, upon a motion to dismiss, to decide the merits where an issue of material fact is in dispute"); *id.* at \*5 ("diametrically opposed versions of the facts must be tested after full and complete discovery, not by a motion to dismiss pursuant to Fed.R.Civ.P. 12(b)(6)") (citations omitted).

<sup>110</sup> 696 F.3d 254 (3d Cir. 2012).

<sup>111</sup> 555 U.S. 438 (2009).

<sup>112</sup> Reckitt Br. at 19 n.12.

miscast plaintiffs' case as a "duty to deal" case, a mischaracterization which the court rejected.<sup>113</sup>

Second, whether or not *Meritor* narrows the Third Circuit's decision in *LePage's Inc. v. 3M*<sup>114</sup> has no effect on the holding in *TriCor*. *TriCor* did not rely on *LePage's* for its ruling rejecting the defendants' arguments that product changes are *per se* legal and immune from antitrust scrutiny. Relying on *Microsoft*, *Berkey Photo*, and *Dentsply*, *TriCor* held that (1) product changes should be examined under a rule of reason approach; (2) plaintiffs were "not required to prove that the new formulations were absolutely no better than the prior version," but rather that "if Plaintiffs show anticompetitive harm from the formulation changes, that harm will be weighed against any benefits presented by Defendants"; and (3) that the test for anticompetitive effect "is not total foreclosure" or whether competitors are barred from "all means of distribution," but whether they are "barred 'from the cost-efficient ones.'"<sup>115</sup> The *TriCor* court did not rely on *LePage's* for any of these rulings.

*Linkline* leaves *TriCor* untouched as well. As another court in the Circuit examining drug antitrust claims has noted,

The Court's rejection of a scheme claim in *Linkline* was mandated by the specifically applicable holdings in *Trinko* and *Brooke Group*. The *Linkline* Court

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<sup>113</sup> *TriCor*, 432 F. Supp.2d at 423-24. Reckitt's reliance on refusal to deal cases such as *Oahu Gas Serv., Inc. v. Pac. Res. Inc.*, 838 F.2d 360, 369 (9th Cir. 1988) and *Goldwasser v. Ameritech Corp.*, 222 F.3d 390, 397 (7th Cir. 2000) is unavailing. Reckitt Br. at 13 n.7. It is precisely the unique "price disconnect" in the marketplace and the ability of a brand manufacturer to "game" the Hatch-Waxman system and deprive generic rivals of the cost-efficient means of distribution that caused Judge Jordan to hold that the finder of fact would need to evaluate the *TriCor* case under the rule of reason. Reckitt's attempt to cast itself as a monopolist who is simply "entitled to compete" or is increasing competition through purported product improvement is something it can argue to the jury. Similarly, this case is not about a competitor's lost profits or injury from "increased competition." See Reckitt Br. at 13 (relying on *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F.Supp. 2d 686, 696-98 (E.D. Pa. 2004) and *Eon Labs Mfg., Inc. v. Watson Pharms., Inc.*, 164 F.Supp. 2d 350, 358 (S.D.N.Y. 2001)). Plaintiffs have repeatedly alleged that Reckitt's conduct here has *decreased* consumer choice and raised prices (*i.e.*, *harmed* competition).

<sup>114</sup> 324 F.3d 141 (3d Cir. 2003) (en banc).

<sup>115</sup> *TriCor*, 432 F. Supp.2d at 422-23 (citations omitted).

did not discuss the sufficiency of other monopolization scheme claims, nor does anything in the *Linkline* decision indicate an intention on the part of the Court to overrule long-established principles concerning the viability of claims alleging an overall scheme to unlawfully maintain a patent monopoly by excluding generic competition.<sup>116</sup>

In a last ditch effort, Reckitt claims that this case is indistinguishable from *Walgreen Co. v. AstraZeneca Pharms. L.P.*<sup>117</sup> — but *Walgreen* actually *supports* plaintiffs’ position here. The *Walgreen* court found that the plaintiffs there failed to allege that the defendants’ conduct had led to a reduction in consumers’ choices (as the defendants there did not withdraw the older branded product from the market, did not make false representations about the older product, and brought a lower-priced over the counter version of the product to the market) and that the plaintiffs had not alleged coercion.<sup>118</sup> The direct purchaser plaintiffs’ allegations here stand in stark contrast. Reckitt’s motion should be denied.

**B. Antitrust law prohibits Reckitt from impairing competition by sabotaging the FDA-mandated joint SSRS program.**

The direct purchaser plaintiffs allege that, as part of its anticompetitive scheme to impede generic Suboxone competition, Reckitt obstructed market entry of generic Suboxone tablets in violation of Section 2 of the Sherman Act by actively and deliberately undermining the mandatory Single Shared REMS process (the “SSRS”) that the FDA ordered all Suboxone tablet manufacturers to complete.<sup>119</sup> Reckitt strung the process along, participating in bad faith merely to subvert the process and thereby delay FDA approval and market entry of generic Suboxone tablets. Reckitt misled the ANDA filers (its competitors) and the FDA for nearly ten months

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<sup>116</sup> *In re Neurontin Antitrust Litig.*, MDL No. 1479, 2009 WL 2751029, \*16 (D.N.J. 2009).

<sup>117</sup> 534 F. Supp.2d 146 (D.D.C. 2006).

<sup>118</sup> *Id.* at 151-52.

<sup>119</sup> See Compl. ¶¶ 10, 12, 57, 58, 59, 60, 98, 101, 102, 105-12.

regarding Reckitt's supposed participation in the SSRS process; this active deception and delay — not some passive refusal to deal — slowed the creation of an SSRS, delayed final ANDA approval and generic market entry, and allowed Reckitt to unlawfully maintain its monopoly and significantly impair competition. This is actionable anticompetitive conduct; had Reckitt complied with the law and acted in good faith, generic ANDA filers could have received earlier approval of the SSRS or a generics-only SSRS, paving the way for earlier entry of lower-priced generic Suboxone tablets.<sup>120</sup> In the only other antitrust case involving a REMS program that plaintiffs know of, a court in this district denied a motion to dismiss.<sup>121</sup>

**1. Reckitt's conduct is actionable under Section 2.**

Reckitt argues that plaintiffs (1) are trying to imply a private right of action from 21 U.S.C. § 355-1(f)(8), the portion of the FDCA that prohibits Reckitt's challenged conduct, (2) are complaining about Reckitt's refusal to deal with its would-be generic competitors, or (3) are seeking to impose a duty on Reckitt to “aid [its] rivals.”<sup>122</sup> Plaintiffs, who are masters of their complaint,<sup>123</sup> are doing none of these things. Instead, Plaintiffs are challenging Reckitt's *misconduct* that was designed to, and did, string its would-be generic competitors along even as

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<sup>120</sup> See *Broadcom Corp. v. Qualcomm, Inc.*, 501 F.3d 297, 308 (3d Cir. 2007) (anticompetitive conduct “is generally defined as conduct to obtain or maintain monopoly power as a result of competition on some basis other than the merits”).

<sup>121</sup> In *Lannett Co. v. Celgene Corp.*, No. 08-3920 (E.D. Pa. filed Aug. 15, 2008) (Savage, J.) a brand drug manufacturer, Celgene, faced a claim under Section 2 of the Sherman Act after refusing to provide drug samples to a generic manufacturer, citing a REMS program limitation. Without the samples, the generic manufacturer could not perform studies required for its ANDA. Celgene argued that it could not provide the samples under its REMS and moved to dismiss the antitrust claim under the same “refusal to deal” principle Reckitt argues here relying on *Verizon* and *Trinko*. Without a written opinion, Judge Savage denied Celgene's motion to dismiss. See Order, No. 08-cv-3920, at ECF No. 27 (May 13, 2010) and Order, No. 08-cv-3920, at ECF No. 42 (March 31, 2011).

<sup>122</sup> Reckitt Br. at 23.

<sup>123</sup> See *The Fair v. Kohler Die & Specialty Co.*, 228 U.S. 22, 25 (1913) (“the party who brings suit is master to decide what law he will rely upon”); *Erie Ins. Exch. v. Erie Indem. Co.*, 722 F.3d 154, 159 (3d Cir. 2013) (“Plaintiffs are the masters of their complaints”).

Reckitt feigned cooperation with them. Plaintiffs are complaining that Reckitt pretended to cooperate, but instead ran the clock to delay and obstruct the progress of the SSRS process, solely to maintain its monopoly.

Specifically, plaintiffs allege that Reckitt failed to attend meetings, failed to substantively participate in other meetings, failed to send appropriate personnel to meetings, and insisted that the generics accede to various unprecedented and unreasonable commercial demands before Reckitt would agree to participate in the substance of the SSRS process, including a requirement that the generic companies agree to share the costs of all product liability suits involving Suboxone, including those that pre-dated the entry of the generic products.<sup>124</sup> Plaintiffs allege that although Reckitt again advised the FDA that it would cooperate in June 2012, it nevertheless continued its charade. For instance, Reckitt refused to sign a group agreement unless it was given veto authority for all issues relating to administration of the SSRS, and demanded something that it knew the generic companies could not do: contractually assume liability for all Suboxone product liability claims, regardless of fault.<sup>125</sup> Had Reckitt sincerely been concerned about sharing confidential information, the law provided a path for Reckitt to act in good faith and promptly seek a waiver of the requirement of a single shared REMS system.<sup>126</sup> Because Reckitt's concern was delaying ANDA approval, it did not do so.

Plaintiffs do not argue that Reckitt's conduct is a refusal to deal. Rather, Reckitt's conduct is conduct designed to maintain its monopoly power based on something other than competition on the merits. The laws promoting market entry of generic drugs are intended to

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<sup>124</sup> *Id.* ¶¶ 106-07 and Compl. Ex. E (Amneal Letter to FDA).

<sup>125</sup> *Id.* ¶¶ 108-09.

<sup>126</sup> Reckitt Br. at 27.

encourage competition.<sup>127</sup> Misconduct to game those laws and regulations uncontroversially — and not under any “refusal to deal” theory — gives rise to antitrust claims under § 2, including actions that abuse judicial and regulatory processes.<sup>128</sup> The Third Circuit has recognized that there is an almost-limitless variety of anticompetitive conduct that is actionable under Section 2, including “unfair, tortious conduct targeting competitors” — precisely the conduct Reckitt engaged in here.<sup>129</sup> Moreover, Reckitt is an alleged monopolist.<sup>130</sup> As the leading antitrust treatise explains, the “capacity to impair the opportunities of rivals can also make an act ‘exclusionary’ when undertaken by a monopolist.”<sup>131</sup> Reckitt’s conduct is actionable under § 2.

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<sup>127</sup> See e.g. *Caraco*, 132 S. Ct. at 1676 (principal purpose of the Hatch-Waxman Act is to “speed the introduction of low-cost generic drugs to market”); *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2228, 2234 (2013) (Hatch-Waxman has “general procompetitive thrust” and a process for encouraging generic competition that allows “the generic to piggy-back” on the brand drug’s approval efforts).

<sup>128</sup> *Cal. Motor Transp. Co. v. Trucking Unlimited*, 404 U.S. 508, 512-513 (1972) (misuse of state legal and regulatory processes in order to deprive competitors of meaningful access stated claim); *Walker Proc. Equip. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 177 (1965) (defendant attempted to monopolize by threatening to and pursuing legal enforcement of patent procured by fraud); *In re Bupirone*, 185 F. Supp. 2d 363 (S.D.N.Y. 2002) (improper listing of patent in FDA Orange Book in violation of Hatch-Waxman Act and then enforced against rivals actionable under § 2); *Tricor*, 432 F. Supp.2d 408 (“product hopping” as a manipulation of the Hatch-Waxman regulatory scheme can violate the antitrust laws). Recently, the Tenth Circuit observed that filing false papers with regulators could be actionable exclusionary conduct under Section 2, and not under a “refusal to deal” theory. *Novell, Inc. v. Microsoft Corp.*, No. 12-4143, 2013 WL 5303259, \*10 (10th Cir. Sept. 23, 2013).

<sup>129</sup> “Anticompetitive conduct can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties.” *LePage’s*, 324 F.3d at 152. See *Meritor*, 696 F.3d at 278-79 (noting that “[t]he law has long recognized forms of exclusionary conduct that do not involve below-cost pricing, including . . . unfair tortious conduct targeting competitors”). See also *Byars v. Bluff City News Co.*, 609 F.2d 843, 854 (6th Cir. 1979) (holding that defendant’s “dirty tricks” against a smaller company attempting to compete against it, may be deemed exclusionary, including removing plaintiff’s periodicals from sales racks at various retail outlets, covering up plaintiff’s periodicals on racks so that prospective buyers could not see them, and disparaging plaintiff, his financial condition and the magazine’s financial condition); *Conwood Co., L.P. v. U.S. Tobacco Co.*, 290 F.3d 768 (6th Cir. 2002) (unfair tortious conduct targeting competitors gives rise to claim).

<sup>130</sup> Reckitt does not resist that moniker. “Reckitt had attempted to work with the generics for less than a year, and would have lost money if the attempt had succeeded. No monopolist can be required to shoot itself in the foot.” Reckitt Br. at 26.

<sup>131</sup> Areeda & Hovenkamp ¶ 782. “[B]ehavior that otherwise might comply with the antitrust law may be impermissibly exclusionary when practiced by a monopolist.” *Dentsply*, 399 F.3d at 187. See also *cont’d...*

Nor do plaintiffs seek to imply a right of action from the FDCA. It is certainly true that Congress anticipated that brand drug manufacturers like Reckitt would have the incentive to “game” the regulatory system by using an FDA-mandated REMS or SSRS program to delay ANDA approval. Consequently, Congress enacted Section 505-1(f)(8) of the FDCA,<sup>132</sup> explicitly prohibiting a brand drug manufacturer from using elements of a REMS program “to block or delay approval of” generic drug ANDAs.<sup>133</sup> However, the statute need not supply a private right of action for Reckitt’s conduct to be redressable. There is already a statute that supplies a private right of action to redress Reckitt’s conduct here. That statute is the Clayton Act, 15 U.S.C. § 15, through which violations of § 2 of the Sherman Act are made privately actionable.<sup>134</sup>

**2. Even if construed as a “refusal to deal,” Reckitt’s conduct is still actionable.**

Even if this case did implicate the “duty to deal” line of cases Reckitt points to, dismissal would still be inappropriate. The Supreme Court held in *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.* that “the right to refuse to deal with other firms does not mean that the right is unqualified” and “a firm’s unilateral refusal to deal with its rivals can give rise to antitrust

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*LePage’s*, 324 F.3d at 151-52 (a “monopolist is not free to take certain actions that a company in a competitive . . . market may take”).

<sup>132</sup> 21 U.S.C. § 355-1(f)(8) states: “No holder of approved cover application shall use any element to assure safe use required by the Secretary under this subsection to block or delay approval of an application under section 355(b)(2) or (j) of this title or to prevent application of such element under (i)(1)(B) of this section to a drug that is the subject of an abbreviated new drug application.”

<sup>133</sup> Compl. ¶ 60. Reckitt claims that § 355-1(f)(8) does not apply to its conduct. Reckitt Br. at 26-27. Reckitt is wrong. It suffices to point out that the FDA warned Reckitt that “actions designed to ‘block or delay’ approval of [the generics’] ANDAs, or otherwise preventing the application of an SSRS to an ANDA drug, were prohibited” by this law. See Compl. ¶¶ 107-108. FDA’s interpretation of the FDCA is entitled to deference. *NVE Inc. v. HHS*, 436 F.3d 182, 186 (3d Cir. 2006).

<sup>134</sup> See *Otter Tail Power Co. v. United States*, 410 U.S. 366, 377 (1973). Without a clear grant of immunity, the ordinary principles of antitrust law apply, and a regulated monopolist’s anticompetitive conduct may violate the Sherman Act. *Id.* at 374, 377.

liability.”<sup>135</sup> Under *Aspen Skiing*, a monopolist may be held liable for unilaterally refusing to deal with a competitor if “a firm has been attempting to exclude rivals on some basis other than efficiency,” or if it is acting with the “purpose to create or maintain a monopoly[.]”<sup>136</sup> For instance, in *Aspen Skiing*, the defendants’ termination of a joint ski pass with the plaintiff’s smaller mountain “suggested a willingness to forsake short-term profits to achieve an anti-competitive end” and was therefore anticompetitive.<sup>137</sup> In *Multistate Legal Studies*, the Tenth Circuit found that deliberate scheduling conflicts created by the providers of comprehensive bar review courses, in an attempt to monopolize the market for supplemental bar review courses, were unjustified and anticompetitive refusals to deal.<sup>138</sup> In *MetroNet Services Corp. v. Qwest Corp.*, the Ninth Circuit held that “[a]n offer to deal with a competitor only on unreasonable terms and conditions can amount to a practical refusal to deal.”<sup>139</sup> In *Safeway v. Abbott Labs.*,<sup>140</sup> the court held that the defendant’s 400% price increase of the prescription drug Norvir to ensure the successful launch of its proprietary competitive drug Kaletra effectively constituted an actionable refusal to deal. By setting such unattractive terms, Abbott actionably refused to deal with its competitors.<sup>141</sup> In much the same way, Reckitt required the generic companies in this case to agree to unreasonable terms and conditions as it strung them along, running the clock in SSRS negotiations. Therefore, even if misconstrued as a “refusal to deal” claim, the plaintiffs’

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<sup>135</sup> 472 U.S. 585, 601 (1985) (“the right to refuse to deal with other firms does not mean that the right is unqualified”).

<sup>136</sup> *Id.* at 605, 602.

<sup>137</sup> *Id.* at 601. *See also Trinko*, 540 U.S. at 408 (“Under certain circumstances, a refusal to cooperate with rivals can constitute anticompetitive conduct and violate §2.”).

<sup>138</sup> 63 F.3d 1540, 1553 (10th Cir 1995).

<sup>139</sup> 383 F.3d 1124, 1132 (9th Cir. 2004).

<sup>140</sup> 761 F. Supp. 2d 874 (N.D. Cal. 2011).

<sup>141</sup> *Id.* at 892-95.

allegations regarding Reckitt's SSRS misconduct may not be dismissed.<sup>142</sup>

**C. Reckitt's sham petition had neither merit nor any chance of success; it was simply part of a scheme to unlawfully delay generic competition.**

Petitioning activity to the government is a sham, and therefore not protected from antitrust liability, if the activity is objectively baseless and done with the subjective motivation to interfere with the business relationships of a competitor. The Complaint alleges that Reckitt filed a baseless petition with the FDA to delay approval of generic Suboxone tablets; no reasonable entity could realistically expect success on the merits of that petition; and Reckitt pursued the petition with the subjective intent of delaying generic competition.

In *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, the Supreme Court articulated the two-prong test for determining whether petitioning activity constitutes a sham and is therefore not entitled to antitrust protection. The petitioning activity must be: (1) "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits"; and (2) subjectively motivated to interfere directly with the business of a competitor as an anticompetitive weapon.<sup>143</sup> "The question whether petitioning activity is a sham 'is generally a question of fact for the jury[.]'"<sup>144</sup>

Reckitt waited until September 25, 2013 to file a sham petition with the FDA, as the generic Suboxone tablet filers prepared to submit their generics-only SSRS to the FDA and complete one of the last steps before approval of their ANDAs. Reckitt argues that its citizen

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<sup>142</sup> Reckitt places mistaken reliance on two telecommunications cases arising under the Federal Communications Act — *Trinko* and *Linkline* — to argue it cannot be required to deal with its competitors. Neither aids Reckitt. This case is nothing like *Trinko* or *Linkline* because the generic Suboxone ANDA filers did not seek to be engaged in any commercial relationship with Reckitt.

<sup>143</sup> 508 U.S. 48, 60-61 (1993).

<sup>144</sup> *In re Flonase Antitrust Litig.*, 795 F.Supp.2d 300, 310 (E.D. Pa. 2011) (quoting *Indep. Taxicab Driver's Emps. v. Greater Hous. Transp. Co.*, 760 F.2d 607, 612 n.9 (5th Cir. 1985)).

petition was not objectively baseless as a matter of law. The Complaint alleges, however, that the petition was a sham; that none of Reckitt's requests had merit; and that Reckitt had no reasonable expectation of success. Reckitt instead filed the objectively baseless petition to delay ANDA approval and entry of generic competition for Suboxone tablets and to artificially extend the Suboxone monopoly.<sup>145</sup> Plaintiffs specifically allege why the petition was baseless:

- *Reckitt asked the FDA to take actions the agency had no authority to take — and was specifically prohibited by the FDCA from taking.* For example, the FDA can only require that ANDA filers adopt FDA-approved materials such as labeling and REMS for the brand drug; it had no authority to grant Reckitt's request that ANDAs for generic Suboxone include a voluntary targeted pediatric exposure education program separate from the labeling or REMS.<sup>146</sup>
- *Reckitt presented no evidence supporting its claims.* Reckitt provided no well-controlled, statistically significant scientific support for its requests: "the Petition was not supported by evidence that voluntary educational programs or unit-dose packing caused a decline in accidental pediatric exposures." Likewise, Reckitt provided no data that only unit-dose packaging could be safely used.<sup>147</sup> The FDA can only act on such support.<sup>148</sup>
- *The FDA questioned Reckitt's timing.* Reckitt sought delay of ANDA approval until the FDA determined whether Suboxone tablets were withdrawn from the market for safety reasons. But Reckitt had not yet withdrawn the tablets and had just the month before, "indicated . . . that the Suboxone REMS, which is designed to mitigate the

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<sup>145</sup> Compl. ¶ 114.

<sup>146</sup> Compl. ¶¶ 116-19. Reckitt argues that it had a reasonable chance of success on its request that the FDA require the generic manufacturers to adopt labeling for generic Suboxone different from Reckitt's labeling for brand Suboxone — in violation of federal regulations — because "the FDA was considering altering that requirement." Reckitt Br. at 37 (citing U.S. Br. at 15 n.2, *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013), available at 2013 WL 314460). But Reckitt does not describe how it can see into the future: the United States' brief was filed *four months after* Reckitt filed its petition to the FDA, and Reckitt made no mention of this potential alteration in its petition.

<sup>147</sup> FDA's request for additional information does not, however, mean that Reckitt's petition had a reasonable chance of success. *See, e.g., Astellas Pharma US, Inc. v. FDA*, 642 F.Supp.2d 10, 20 (D.D.C. 2009) (in denying the brand company's motion for a restraining order intended to block final approval of an ANDA, the district court noted that "[a]lthough the plaintiff provides ample support for the uncontroversial proposition that supplemental testing could reveal additional information pertinent to bioequivalency, it has made no showing that the testing guidelines established by the FDA were insufficient to meet its statutory obligation to ensure the safety and efficiency [*sic*, efficacy] of new drugs").

<sup>148</sup> Compl. ¶¶ 124-25, 130.

risks associated with that drug, had been successfully implemented and that it was not proposing any changes.”<sup>149</sup>

- *The FDA denied the petition in full.*<sup>150</sup> Despite taking its charges seriously, “review[ing] several additional data sources in an attempt to substantiate the Petition’s claims” and using the full 150 days to respond in a seventeen-page single-spaced letter, the FDA found no merit in any of Reckitt’s requests and denied all of them.<sup>151</sup>
- *The FDA suspected anticompetitive behavior drove the petition.* The FDA referred the entirety of Reckitt’s behavior to the Federal Trade Commission for antitrust investigation and evaluation.<sup>152</sup>

Without supporting facts and law, Reckitt’s petition was utterly baseless and stood no chance of success.<sup>153</sup> Rather, Reckitt filed the petition as part and parcel of a scheme to delay and obstruct FDA approval of ANDAs for generic Suboxone tablets. “A court should only rule on the objective baselessness prong as a matter of law ‘[w]here there is no dispute over the predicate facts of the underlying [petitions].’”<sup>154</sup> Here, Reckitt’s arguments illustrate, those disputes exist.

Reckitt’s reliance on Section 505q of the FDCA gets it no further. The FDA has explained that the September 2007 amendments to the FDCA did little to speed the process:

[b]ased on the petitions that FDA has seen [since the enactment of the September 2007 amendments] . . . the agency is concerned that section 505(q) may not be discouraging the submission of petitions that do not raise valid scientific issues and are intended primarily to delay the approval of competitive drug products. . . . FDA remains concerned about the resources required to respond to

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<sup>149</sup> Compl. at Ex. G, p. 15.

<sup>150</sup> Compl. ¶ 141.

<sup>151</sup> Compl. at Ex. G, p. 10. *See id.* at ¶ 141.

<sup>152</sup> Compl. ¶¶ 141-42.

<sup>153</sup> *See In re Flonase Antitrust Litig.*, 2012 WL 5363118, \*3-5 (E.D. Pa. Nov. 1, 2012) (allowing former Commissioner of the FDA, David A. Kessler, M.D., to render expert opinions that “FDA is a data-driven organization” and that “a citizen petitioner can move the FDA to adopt new policies by presenting scientific and medical data that is ‘clinically meaningful’”). Here, Reckitt presented no clinically meaningful evidence, making the petition “dead on arrival.”

<sup>154</sup> *Flonase*, 795 F.Supp.2d at 310 (quoting *PRE*, 508 U.S. at 60-61).

505(q) petitions within the statutory deadline at the expense of completing the other work of the agency.<sup>155</sup>

Indeed, Reckitt includes a petition denial issued by the FDA that expressly recognizes that petition filings can and do still cause the delay of ANDA approvals notwithstanding the language of the 2007 amendments.<sup>156</sup> The fact that the FDA referred the entirety of Reckitt's behavior to the FTC for antitrust investigation and evaluation suggests a similar conclusion here.<sup>157</sup>

**D. Reckitt's motion must be denied even if portions of plaintiffs' claims would not be sufficient by themselves.**

The direct purchaser plaintiffs allege three independently actionable claims — for anticompetitive “product hopping,” sham petitioning, and abuse of the SSRS process.<sup>158</sup> Each element of Reckitt's misconduct worked to delay generic competition unlawfully. The direct purchaser plaintiffs also allege the multiple coercive and anticompetitive tactics had a “synergistic effect” as an overarching anticompetitive scheme greater than the sum of its parts<sup>159</sup>; by combining each prong, Reckitt created more delays and impeded more competition than it could using each prong independently.

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<sup>155</sup> Fourth Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2011, dated Dec. 14, 2012, at 6, attached as Ex. C to Reckitt Br.

<sup>156</sup> Reckitt Br. at 33 and Ex. D.

<sup>157</sup> To the extent Reckitt is arguing that the petition did not cause any delay in ANDA approvals and generic competition, that argument is not proper on a motion to dismiss. *E.g.*, *Rivas v. City of Passaic*, 365 F.3d 181, 193 (3d. Cir. 2004) (“the presence of the requisite causation is normally a question of fact for the jury”); *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899, 902 (7th Cir. 2004) (“a prediction that the plaintiff will be unable to meet its challenges [on causation] is not a good reason to dismiss a complaint under Rule 12(b)(6)”; *Wortley v. Camplin*, 333 F.3d 284, 295 (1st Cir. 2003) (“proximate cause and intervening cause are usually issues for the jury to decide.”).

<sup>158</sup> Compl. at Claims 2-4.

<sup>159</sup> *Id.* at Claim 1. *See also City of Groton v. Conn. Light & Power Co.*, 662 F.2d 921, 929 (2d Cir. 1981).

Contrary to Reckitt's arguments, The Third Circuit has clearly recognized that monopolists can violate Section 2 by engaging in such an overall scheme to monopolize. In *LePage's*, a monopolist engaged in a series of acts, the anticompetitive effect of which became "most apparent when . . . considered as a whole." Recognizing this, the Third Circuit, sitting en banc, refused to view each part of defendants' conduct in isolation, but examined the entire course of conduct, holding:

[t]he relevant inquiry [in monopolization cases] is the anticompetitive effect of [the defendant's] exclusionary practices considered together. As the Supreme Court recognized in *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962), the courts must look at a monopolist's conduct taken as a whole rather than considering each aspect in isolation.<sup>160</sup>

Based on cases like *LePage's*, several recent cases have specifically upheld the validity of "overall scheme" claims in the Hatch-Waxman context.<sup>161</sup> It is well-established that such a scheme can violate the antitrust laws even if some — or even all — of the elements of that

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<sup>160</sup> 324 F.3d at 162.

<sup>161</sup> See, e.g., *In re Remeron Antitrust Litig.*, 335 F. Supp. 2d 522, 528 (D.N.J. 2005) (under *LePage's*, "the relevant inquiry is the anti-competitive effect of [the defendant's] exclusionary practices considered as a whole"); *SmithKline Beecham Corp. v. Apotex Corp.*, 383 F. Supp. 2d 686, 70-03 (E.D. Pa. 2004) (sustaining complaint on grounds of "a larger scheme to maintain the monopoly in the market," even though certain conduct itself could not be challenged under antitrust laws); *Biovail Corp. Int'l v. Hoechst AG*, 49 F.Supp. 2d 750, 759 (D.N.J. 1999) (citing *Continental Ore*, denying motion to dismiss, and stating "defendants' behavior will be evaluated, and all inferences will be drawn, in light of the allegations as a whole"). See also *Caldera, Inc. v. Microsoft Corp.*, 72 F. Supp. 2d 1295, 1309 (D. Utah 1999) ("to allow defendant to carve plaintiff's complaint into seven discrete claims that plaintiff never intended to allege as independent claims not only appears to offend the purpose behind § 2, but also turns basic civil procedure principles on their head"); *City of Anaheim v. S. Cal. Edison Co.*, 955 F.2d 1373, 1376 (9th Cir. 1992) ("It would not be proper to focus on specific individual acts of an accused monopolist while refusing to consider their overall combined effect"); *City of Mishawaka v. American Elec. Power Co.*, 616 F.2d 976, 986 (7th Cir. 1980) (rejecting the argument that the court must consider each separate aspect of defendants' conduct "in a vacuum," because it is "the mix of the various ingredients of [the defendant's] behavior in a monopoly broth that produces the unsavory flavor.").

scheme are not independently actionable.<sup>162</sup> Reckitt's suggestion otherwise "is contrary to the law."<sup>163</sup>

The Complaint here alleges that Reckitt knew the significant competitive threat posed by generic rivals, and undertook an overall scheme to extend and protect Suboxone's dominance in by delaying and impeding generic entry. When evaluated as a whole, plaintiffs have clearly alleged that this scheme was exclusionary and anticompetitive, in violation of § 2. Such an exclusionary scheme is illegal, even if one assumes — contrary to fact — that each of the acts comprising the scheme may be lawful if analyzed separately.

**E. The direct purchaser plaintiffs adequately define the market and allege market power.**

In a bid to exceed its page limits, Reckitt incorporated its "relevant market" argument against the end-payors into its motion against the direct purchasers. Consequently, the direct purchaser plaintiffs incorporate by reference the end-payors' responsive argument.<sup>164</sup>

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<sup>162</sup>See *Am. Tobacco Co. v. U.S.*, 328 U.S. 781, 809 (1946) ("It is not of importance whether the means used to accomplish the unlawful objective are in themselves lawful or unlawful"); *Borden, Inc. v. FTC*, 674 F.2d 498, 513 (6th Cir. 1982) ("It is not essential to a finding of monopolization ... that acts or practices used to maintain monopoly power be in themselves independently unlawful."); *Biovail*, 49 F.Supp. 2d at 766 ("Defendants' argument that conduct cannot form the basis for an antitrust violation if it is not wrongful for reasons extrinsic to the antitrust laws is simply incorrect."); *Conwood Co. v. U.S. Tobacco Co.*, 2000 WL 33176064, at \*4 (W.D. Ky. Aug. 10, 2000) (finding that even if "no one instance of improper conduct standing alone would lead to §2 liability," the actions, taken together, "show a a pattern of exclusionary behavior sufficient to support a jury verdict"). See also *Aspen Highlands Skiing Corp. v. Aspen Skiing Co.*, 738 F.2d 1509, 1522 n.18 (10th Cir. 1984), *aff'd*, 472 U.S. 585 (1985) (considering record "as a whole" and concluding that it was not necessary for plaintiff to prove that each allegedly anticompetitive act was itself sufficient to demonstrate an abuse of monopoly power).

<sup>163</sup> *TriCor*, 432 F. Supp.2d at 428.

<sup>164</sup> Through an oversight, several of the averments of the *Rochester Drug Co-Operative, Inc.* complaint (ECF No. 1 at 13-1164) — in particular those at ¶¶ 98-104 — were unintentionally excluded from the direct purchasers' Consolidated Amended Complaint (ECF No. 47 at 13-2445). These averments are virtually identical to the ones appearing as ¶¶ 153-159 in the end-payors' consolidated amended complaint (EFC No. 48 at 13-2445). The direct purchaser plaintiffs regret this oversight, and intend to file a Consolidated Second Amended Complaint to re-insert those averments upon the disposition of this motion.

## CONCLUSION

The Complaint contains painstaking factual detail supporting each element of plaintiffs' claims. Reckitt's defenses to these well-pleaded facts or its alternate interpretation of those facts provide no basis to dismiss the Complaint. Plaintiffs respectfully request that the Court deny Reckitt's motion in its entirety. If the Court is inclined to grant Reckitt's motion in any respect, plaintiffs respectfully request leave to replead.

Dated: October 15, 2013

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

On this day, I caused a copy of this document to be served on all counsel of record via the court's CM/ECF system.

/s/ Peter Kohn  
PETER KOHN

Dated: October 15, 2013